

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re:)	MDL No. 1457
)	Civil Action No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY)	Subcategory No. 06-11337
AVERAGE WHOLESALE PRICE)	
LITIGATION)	Hon. Patti B. Saris
)	
)	

THIS DOCUMENT RELATES TO:

*United States ex rel Ven-A-Care of the
Florida Keys, Inc. v. Schering Corporation,
Schering-Plough Corporation and
Warrick Pharmaceuticals Corporation*
Civil Action No. 09-CV-10547

*United States ex rel Ven-A-Care of the
Florida Keys, Inc. v. Schering Corporation,
Schering-Plough Corporation and
Warrick Pharmaceuticals Corporation*
Civil Action No. 00-10698

AMICUS CURIAE
OF THE STATES OF

**WISCONSIN, ALASKA, IDAHO,
ILLINOIS, KENTUCKY, AND MISSISSIPPI**

**in Opposition to Entry of the Proposed Order Approving Settlement and Dismissal
with Prejudice of Schering-Plough Corporation, Schering Corporation and Warrick
Pharmaceuticals Corporation**

Each of the above-named States (“the States”) currently has litigation pending against one or more of the defendants (hereinafter “defendants”).¹ The States respectfully request that this Court deny approval of the proposed Order Approving Settlement and Dismissal with Prejudice of Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation (“Proposed Order”).² As outlined below, the States believe that entry of the Proposed Order would impermissibly and inappropriately affect the current state prosecutions of the defendants and would operate to the detriment and disadvantage of States’ interests.

The above States all have alleged that by publishing a price greater than the actual and truthful average of wholesale price, the defendants violated state law. The laws of the *amicus curiae* States do not recognize or allow the publication of a price in excess of the actual price.³ There is no safe harbor under these state laws for prices that fall within what has been called the “thirty percent yardstick.” In the litigation pending in these state courts, the States seek as damages all payments made by the Medicaid program in excess of what should have been paid had the defendants reported truthful prices. The States also seek, *inter alia*, injunctive relief on behalf of their consumers.

¹ On June 3, 2004, the State of Wisconsin filed a lawsuit against Schering Plough Corporation and Warrick Pharmaceuticals Corporation in Dane County Circuit Court, Wisconsin, case no. 04-CV-1709.

² The Proposed Order was supported by the Joint Memorandum in Support of Motion for Approval of the Settlement Between California, Florida, and Relator Ven-A-Care of the Florida Keys on Behalf of Itself and the United States and Schering-Plough, Schering, and Warrick, filed on August 7, 2009 [hereinafter “Joint Memorandum”].

³ For example, Wis. Stat. §100.18(10)(b) provides: “It is deceptive to represent the price of any merchandise as a manufacturer’s or wholesaler’s price, or a price equal thereto, unless the price is not more than the price which retailers regularly pay for the merchandise. The effective date of this subsection shall be January 1, 1962.” Idaho has a Consumer Protection Rule with similar language. *See* IDAPA 04.02.01.066.04.

Regarding the Proposed Order, the States agree with objectors that the proposed findings constitute an improper “advisory opinion.” (Joint Memorandum at 12.) Moreover, the Settling Parties attempt to analogize this FCA case with a class action, noting that in “approving class action settlements pursuant to Rule 23, ... courts often enter findings of fact and conclusions of law concerning the fairness, adequacy, and reasonableness of the proposed settlement to the class.” (Joint Memorandum at 11.) However, the “purpose of Rule 23(e) [findings of fact] is to protect the unnamed members of the class from unjust or unfair settlements affecting their rights.” *In re Syncor ERISA Litigation*, 516 F.3d 1095, 1100 (9th Cir. 2008). Here, by contrast, the Settling Parties’ proposed findings are meant to disenfranchise third parties.

In the following respects, the Proposed Order is directly contrary to the States’ interests, inconsistent with state law, and conflicts with the States’ prosecutions of the defendants and the results obtained in various state prosecutions⁴:

A. The defendants make no secret that they believe they can use the Proposed Order to extinguish the States’ prosecutions of the defendants for the federal share of the States’ claims now pending in state courts. (Joint Memorandum at 5-6.)⁵ Although Defendants and the Relator suggest that this settlement is fair, the Parties ignore the fact that under certain state laws, the federal government (and indirectly the taxpayers) are entitled to significantly greater monetary recovery than what has been calculated and apparently agreed to by Florida, California, and the Relator.

⁴ Wisconsin tried to jury verdict its case against Pharmacia in February, 2009.

⁵ Whether this belief is correct or not is almost beside the point since it is clear that defendants will create substantial mischief and confusion in the state court by asserting that this Court has extinguished these cases. Even if this argument is ultimately rejected, the States will have to spend huge amounts of time and money putting this argument to rest.

Additionally, the States have expended significant resources attempting to recover these overpayments. No provision is made in the Proposed Order to reimburse the States for their costs associated with their attempts to recover this federal share.

B. Publishing a price for a drug (brand or generic) within the formulaic range of up to 130% of the amount generally and currently paid by wholesalers violates State law as alleged in the States' complaints and as proven at trial against some defendants in various State prosecutions. (*See generally* n. 3). Indeed, the "speed limit" was a creation of the private class action plaintiffs who sought recovery for the most sophisticated industry participants by limiting their damage claim to only spreads in excess of 30%. It is uniformly the case that the state Medicaid programs were unaware that the published AWP's were 20% or 25% higher than the prices actually paid by pharmacies for drugs.

C. Proposed findings of fact Numbers 3 and 4 request findings including the "facts" that Medicaid did not reasonably consider published AWP's that were generally within 30% of the average selling price "to constitute a false or fraudulent statement, or to be misleading, deceptive or unfair," and that Medicaid "could not have reasonably considered AWP's derived based on widely known and industry-standard 20% or 25% mark-ups from [] WACs to be a false or fraudulent statement, and are not misleading, deceptive, or unfair." These "facts" and the other contained in the proposal are disputed by the States.⁶ The defendants likely will attempt to use this Court's order to influence state courts and sway jurors empanelled to hear these state cases.⁷ The defendants have

⁶ Wis. Stat. §49.49(4m), prohibits the publication of false prices regardless of "government knowledge." In February 2009, a jury returned a verdict against Pharmacia finding that the publication of a price in excess of its true and accurate price was deceptive and false and in violation of both §49.49(4m) and Wisconsin's consumer protection statute, §100.18.

⁷ Illinois' case will be tried to a judge, not a jury.

already repeatedly suggested to state court judges that they should adopt the findings and conclusions of this Court. Although no disrespect is intended to this honorable Court, the States would like the opportunity to contest proposed findings of fact Numbers 3 and 4 in state court rather than have this Court's order offered by the defendants as the final word on the matter.

D. As to proposed finding of fact Number 5, requesting a finding that "none of the WACs or AWP's for the Schering-brand drugs analyzed in Exhibit A to the Settlement Agreement constituted false or fraudulent statements, or were misleading, deceptive, or unfair," the States respectfully suggest that whether the WACs and the AWP's in Exhibit A are false, fraudulent, misleading, deceptive or unfair in a particular state is a question of state law to be answered by a fact-finder in state court after hearing all of the evidence in the States' cases against the defendants. The proposed order contains sweeping language that appears intended to apply to the above-named sovereign States and is inconsistent with State law. (*See e.g.*, Wisconsin Statute § 100.18 (10)(b) prohibiting the publication of wholesale prices when retailers are regularly paying less.) It is one thing for this Court to resolve the matter before it in the presence of the parties to the litigation. It is an entirely different matter to make findings of fact that the States respectfully suggest are not true and to which these non-party sovereign States have had no opportunity to contest.

E. Moreover, the settlement releases claims for damages on drugs even where the spread is greater than the 30% "speed limit." There is a consistent pattern of Schering raising the spread on its largest selling drugs above 30% in 2002 and 2003 (see attached examples). This is unaccounted for in the settlement.

F. The parties' "invitation" to the States (*see* Joint Memorandum at 11) to make their objections in federal court and "to present evidence" (*id.* at 12) violates the States' sovereign immunity and is an indirect attack on the orders of the various federal courts remanding the States' cases back to state court. The States respectfully decline to litigate their state law cases in federal court.

In conclusion, the States request that the Court deny approval of the Proposed Order so that the States can continue their enforcement actions against these defendants without the possibility that the order will be used as grounds for defense or dismissal of the claims in state court.

Dated this 21st day of August, 2009.

Respectfully submitted,

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